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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/324,465	06/02/99	GLUCKSMANN M	5800-2A

000826
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EXAMINER	
WANG, A	
ART UNIT	PAPER NUMBER
1635	11

DATE MAILED: 02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/324,465	Applicant(s) GLUCKSMANN ET AL.	
	Examiner Andrew Wang	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,9-14,18-20,22-30 and 33-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,9-14,18-20,22-30 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

Response to Arguments an Amendments

1. Rejection of claims 2, 9-14, and 18-20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of applicants amendments filed 4 December 2000.

2. Claims 2, 9-14, 18-20, 22-30, and 33-37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 73, 74, 81, and 88-96 of copending Application No. 09/464,685. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims in both applications are drawn to assay methods using an antibody specific for SEQ ID NO: 1 as well as agents, including antibodies which modulate activity of SEQ ID NO: 1 for the same reasons of record as set forth in the Office action mailed 25 August 2000.

Applicants have not provided any substantive arguments, in the response filed 4 December 2000, addressing said rejection except for a request to hold the rejection in abeyance until the issuance of a notice of allowance after which applicants will file a terminal disclaimer to obviate said rejection.

3. Claims 2, 9-14, 18-20, 22-30, and 33-37 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for the same reasons of record as set forth in the Office action mailed 25 August 2000.

Applicant's arguments filed 4 December 2000 have been fully considered but they are not persuasive. Applicants assert that the claimed invention has a well established utility described in the specification to satisfy 35 U.S.C. 101 since applicants have demonstrated that the disclosed polypeptide is a G-protein coupled receptor (GPCR) and would therefore have utility in the methods of use as disclosed by the specification. Although applicants do indeed provide multiple well established and specific utilities for a GPCR, applicants have not clearly demonstrated that the cloned nucleic acid and its encoded polypeptide is actually a GPCR as was noted in the utility rejection. Without clear guidance confirming the asserted GPCR activity, the claimed isolated antibody and methods of use could not be assessed for its credibility in the asserted utilities specific for GPCRs.

Furthermore, applicants assert that the rejection mis-applies the Revised Interim Utility Guidelines Training Materials since applicants disclosure is analogous to example 10 of the utility guidelines that discloses the utility of a cloned DNA ligase. Although some aspects of example 10 is analogous to applicants disclosure such as the cloning and claiming of a cloned sequence, the crucial aspects are in fact unrelated since the example nucleic acid is a DNA ligase which has a specific and substantial utility namely, ligating DNA molecules. Contrary to example 10, applicants disclose a GPCR which has a multitude of divergent activities unrelated to each other

as was noted in the Office action. Moreover, the claimed GPCR has only been defined by a DRY triplet, putative transmembrane domains, and putative extracellular and intracellular domains which clearly does not provide adequate guidance for determining which of the asserted utilities the cloned sequences can be used as opposed to example 10 which shared a high degree of similarity with a known DNA ligase, having a specific utility, and can therefore presumptively be concluded to be a DNA ligase.

Applicants also assert that high sequence homology is not necessary for determining protein activity as though there is sufficiently high homology in certain domains since it is the domains which confer protein activity, which is allegedly supported by Rossmann et al. (applicants did not provide reference for consideration). Although, the importance of certain domains present on polypeptides is not to be underestimated, the mere presence of said domains do not adequately confer or define specific activities to an isolated polypeptide, particularly to GPCRs which have divergent activities as was discussed above, to assess the credibility of the asserted utilities to be substantial and specific for the claimed sequence.

4. Claims 2, 9-14, 18-20, 22-30, and 33-37 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended

without undue experimentation for the same reasons of record as set forth in the Office action mailed 25 August 2000.

Applicant's arguments filed 4 December 2000 have been fully considered but they are not persuasive. Applicants assert that the specification provides ample guidance, such as producing antibodies, GPCR assays, drug screening assays, etc..., to practice the claimed invention and that the specification need not read like a production specification, which is noted, but as noted in the utility rejection addressed above, applicants have not provided a specific or substantial utility for the claimed invention, an isolated antibody which binds to a GPCR having SEQ ID NO: 1. Therefore, without a specific or substantial utility for the invention as claimed it would require undue trial and error experimentation for a skilled artisan to first determine a utility for the claimed invention and then proceed to practice the claimed invention in the disclosed utilities.

Furthermore, applicants assert that the applicant need not know the mechanism by which the invention operates, which is noted, but the mechanism of action of the claimed polynucleotides and its encoded protein in the disclosed methods was not being questioned. instead the enablement question was raised since, as was discussed above, the invention lacks a specific or substantial utility for the disclosed polynucleotides and therefore is not enabled for use in the disclosed utilities since the actual activity (not the mechanism of activity) of the polynucleotide and its encoded polypeptide cannot be ascertained based on the instant specification.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is (703) 306-3217. The examiner can normally be reached on Monday to Thursday from 7:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Andrew Wang
February 6, 2001

Andrew Wang
Patent Examiner
Technology Center 1600
ANDREW WANG
PATENT EXAMINER